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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0514]

Guidance for Industry on ANDA's: Impurities in Drug Substances; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''ANDA's: Impurities in Drug Substances." This guidance provides recommendations for including information in abbreviated new drug applications (ANDA's) and supporting drug master files on the content and qualification of impurities in drug substances produced by chemical syntheses for both monograph and nonmonograph drug substances.

DATES: Written comments may be submitted at any time.

ADDRESSES: Copies of this guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of this guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Robert W. Trimmer, Center for Drug Evaluation and Research (HFD–625), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–5848.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''ANDA's: Impurities in Drug Substances." This guidance provides information on (1)

Qualifying impurities found in a drug substance used in an ANDA by a comparison with impurities found in the related *U.S. Pharmacopeia* (USP) monograph, scientific literature, or innovator material; (2) qualifying impurities found at higher levels in a drug substance used for an ANDA than found in the related USP monograph, scientific literature, or innovator material; (3) qualifying impurities in a drug substance used for an ANDA that are not found in the related USP monograph, scientific literature, or innovator material; and (4) threshold levels below which qualification *is not* needed.

In the **Federal Register** of July 24, 1998 (63 FR 39880), FDA announced the availability of a draft version of this guidance. The July 1998 document gave interested persons an opportunity to submit comments through September 22, 1998. On October 19, 1998 (63 FR 55876), in response to requests from the public, the agency reopened the comment period until November 23, 1998. All comments received during the comment period have been carefully reviewed and the guidance was revised, where appropriate.

This level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking *on* the content and qualification of impurities in drug substances produced by chemical syntheses that are used in generic drug products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number

found in brackets in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11-23-99

November 23, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Margaret M. Dotzel
Acting Associate- Commissioner for Policy

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